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Proposed Re-evaluation Decision PRVD2017-13

Peroxyacetic acid and Its Associated End-use Products

Consultation Document

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of the slimicide peroxyacetic acid, the Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing peroxyacetic acid for sale and use in Canada.

An evaluation of available scientific information found that products containing peroxyacetic acid do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of peroxyacetic acid uses, new risk-reduction measures are proposed to be included on the labels of all products. This proposal affects all end-use products containing peroxyacetic acid registered in Canada.

This Proposed Re-evaluation Decision (PRVD) is a consultation document[1] that summarizes the science evaluation for peroxyacetic acid and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The 'Overview' describes the regulatory process and key points of the evaluation, while the 'Science Evaluation' provides additional technical information on the assessment of peroxyacetic acid.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What is Peroxyacetic Acid?

Peroxyacetic acid is a slimicide co-formulated with hydrogen peroxide for control of algal, bacterial, fungal and yeast growth in pulp and paper mills, and bacterial growth in recirculating cooling water systems, sewage and wastewater effluents in treatment plants, and on-shore oil and gas field well operations. Products containing peroxyacetic acid can be applied continuously or intermittently using closed transfer systems.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Peroxyacetic Acid Affect Human Health?

Peroxyacetic acid is unlikely to affect your health when used according to the label directions.

Potential exposure to peroxyacetic acid may occur through the diet (food and water) or when handling products containing peroxyacetic acid. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed.

Peroxyacetic acid is considered to be slightly acutely toxic by the oral and dermal routes, and moderately acutely toxic by the inhalation route. It is corrosive to both skin and eyes.

Due to the rapid degradation of peroxyacetic acid, the hazard posed by products containing this active ingredient is mostly of an acute nature.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is not of concern.

There are no residential uses of peroxyacetic acid nor is it expected that commercial application would occur in residential areas.

Exposure to bystanders is not expected based upon the registered use pattern and is not expected to be of concern.

Occupational Risks From Handling Products Containing Peroxyacetic Acid

Occupational risks are not of concern when products containing peroxyacetic acid are used according to the label directions, which include protective measures.

For the assessment of occupational exposure and risks, emphasis has been placed on peroxyacetic acid's potential acute toxicity.

Risk from occupational exposures to workers mixing, loading and applying the slimicide using closed application systems or re-entering treated sites are not of concern under current conditions of use.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary exposure to peroxyacetic through consumption of food commodities in contact with treated paper products is not of concern.

Environmental Considerations

What Happens When Peroxyacetic Acid is Introduced Into the Environment?

Peroxyacetic acid is not expected to pose risks of concern to the environment when used according to the proposed label directions.

Peroxyacetic acid enters the environment following the discharge of effluents. Risk from the discharge of effluent water is not expected to be of concern under current conditions of use. Label amendments are proposed to meet current labelling standards and further protect aquatic habitats.

Peroxyacetic acid breaks down quickly in aquatic environments and is not expected to build-up in water. Peroxyacetic acid is not expected to accumulate in the tissues of organisms.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of peroxyacetic acid, the PMRA is proposing further risk-reduction measures related to the environment for product labels.

Environment

- Environmental precautions label statements
- Directions for use label statements
- Disposal statements

What Additional Scientific Information is Required?

No scientific data are requested at this time.

Next Steps

Before making a final re-evaluation decision on peroxyacetic acid, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on peroxyacetic acid. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Following the re-evaluation announcement for peroxyacetic acid, the registrants of the technical grade active ingredients in Canada indicated that they intended to provide continued support for all uses included on the label of the commercial class end-use products in Canada. Currently registered products containing peroxyacetic acid are listed in Appendix I.

2.0 Use Description of Peroxyacetic Acid

Peroxyacetic acid is a slimicide co-formulated with hydrogen peroxide for the control of algal, bacterial, fungal and yeast growth in pulp and paper mills, and bacterial growth in recirculating cooling water systems and sewage, wastewater effluents in treatment plants, and on-shore oil and gas field well operations. Commercial class products containing peroxyacetic acid can be applied continuously or intermittently using closed transfer systems. There are no domestic-class products containing this active ingredient.

3.0 The Technical Grade Active Ingredient and Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common name		Peroxyacetic acid
Function		Bactericide, Slimicide
Chemical Family		Organic and inorganic peroxide
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	Ethaneperoxoic acid
2	**Chemical Abstracts Service (CAS)**	Peroxyacetic acid
CAS Registry Number		79-21-0
Molecular Formula		$C_2H_4O_3$

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 20-25°C	Peroxyacetic acid: 1.87 kPa 2.5-2.9 kPa for the peroxyacetic acid/hydrogen peroxide solutions
Ultraviolet (UV) / visible spectrum	Does not absorb at $\lambda > 400$ nm
Solubility in water	Completely miscible with water
n-Octanol/water partition coefficient	Log K_{ow} = -1.09 to -0.52
Dissociation constant	pK_a = 8.2

4.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Based on the registered use pattern, exposure to peroxyacetic acid may occur by working as a mixer/loader/applicator, by entering treated sites or handling paper.

The primary toxicology hazard for peroxyacetic acid is considered to be acute in nature, related to the corrosive properties to the eyes and skin. A qualitative approach was taken for the assessment and mitigation of human health exposure and risk. No toxicological endpoints (for example, dermal, inhalation, dietary) for use in quantitative risk assessment have been identified for peroxyacetic acid.

4.1 Toxicological Summary

The toxicological database for peroxyacetic acid, consisting of waiver rationales and published data, is considered of sufficient completeness and scientific quality to define the majority of potential toxic effects associated with peroxyacetic acid.

Peroxyacetic acid is considered to be slightly acutely toxic by the oral and dermal routes, and moderately acutely toxic by the inhalation route. It is corrosive to both skin and eyes, but it is not a dermal sensitizer.

Due to the rapid degradation of peroxyacetic acid, the hazard posed by products containing this active ingredient is mostly of an acute nature. However, several short-term toxicity studies have been conducted with peroxyacetic acid. Reduced food and water consumption was observed in studies conducted with peroxyacetic acid, likely due to the odour and irritant properties of the compounds. There is no available chronic toxicity or carcinogenicity data on peroxyacetic acid.

Developmental toxicity information for peroxyacetic acid is not available. However, based on the available toxicological information, it appears unlikely that treatment related effects will result from maternal exposure to peroxyacetic acid.

4.2 Occupational Exposure

Workers can be exposed to peroxyacetic acid through mixing, loading and applying the slimicide using closed application systems as well as workers re-entering treated sites or handling paper.

4.2.1 Mixer/Loader/Applicator Exposure and Risk

The potential for occupational exposure from the use of products containing peroxyacetic acid in pulp and paper mills and recirculating cooling water systems is expected to be limited, and to occur when connecting or disconnecting the pump hoses to a tote, or in the case of a leak (that is a punctured tote or a leaking pump connection). The risk from potential acute exposure to peroxyacetic acid is currently mitigated through labelling, including personal protective equipment (PPE) requirements (that is goggles or face shield, coveralls, boots and chemical-resistant gloves when handling, and NIOSH-approved respiratory protection if certain exposure level are exceeded), and precautionary statements currently included on product labels such as observance of exposure levels of the active ingredient, observance of precautionary statements to avoid breathing in vapours, and the nature of the closed system where the end-use product is used.

Occupational exposure to peroxyacetic acid when used to treat wastewater and sewage effluent or oil and gas-field well operations can occur when the end-use product containers are connected to the manifold system, and is expected to be by the dermal or inhalation route, or through accidental splash to the eyes. Current personal protective equipment requirements on the end-use product label instruct workers to wear goggles, face shield, protective coveralls, boots and chemical-resistant gloves while transferring and handling the product. In addition, precautionary statements instruct workers to ensure that air concentrations of peroxyacetic acid in the workplace do not exceed exposure levels established by Occupational Health and Safety Authorities in their jurisdiction, and that if values do exceed those levels, they are to wear NIOSH-approved respiratory protection. Other precautionary and hygiene statements on the end-use product label include instructions to not breathe the vapour, to not enter an enclosed area without proper respiratory protection, and to wash thoroughly with soap and water after handling. Worker exposure is expected to be appropriately mitigated through the above mentioned risk reduction measures. Therefore, occupational exposure to peroxyacetic acid is expected to be minimal when workers follow the label directions and potential risk is of no concern. No additional mitigation measures are proposed.

4.2.2 Post-application Exposure and Risk

Since recirculating cooling water systems are closed systems, and because peroxyacetic acid will dissipate rapidly from treated water, occupational post-application exposure to peroxyacetic acid is expected to be negligible.

The use of peroxyacetic acid in pulp and paper mills could result in post-application exposure to workers handling paper; however, based on the rapid degradation of peroxyacetic acid in water, no residues are expected to be present in paper and post-application exposure is expected to be negligible.

There is potential for exposure to peroxyacetic acid used as a sewage and wastewater effluent disinfectant in wastewater treatment plants or used in oil and gas-field well operations during post-application activities such as removing the spent container from the manifold system, and coupling or uncoupling transfer lines. Worker exposure is expected to be appropriately mitigated through the required PPE, and observance of exposure levels and precautionary statements. The label of the registered end-use products include precautionary statements instructing workers to ensure that air concentrations of peroxyacetic acid in the workplace do not exceed exposure levels established by Occupational Health and Safety Authorities in their jurisdiction, and that if values do exceed those levels, they are to wear NIOSH-approved respiratory protection. Other precautionary statements on the end-use product label include instructions to not breathe the vapor and to not enter an enclosed area without proper respiratory protection.

Based on the above, risk from occupational post-application exposure to peroxyacetic acid is not expected to be of concern under current conditions of use. No additional mitigation measures are proposed.

4.3 Non-occupational Exposure

4.3.1 Residential and Bystander Exposure and Risk

No domestic class peroxyacetic acid end-use products are currently registered in Canada. Commercial class products containing peroxyacetic acid are not expected to result in residential or bystander exposure: peroxyacetic acid is used in a closed system in wastewater treatment plants and bystander exposure from peroxyacetic acid use in pulp and paper mill systems and recirculating cooling water systems is also not anticipated.

4.3.2 Dietary Exposure and Risk

Dietary exposure to peroxyacetic acid may occur from its use in pulp and paper mill systems since the product labels allow use in the manufacture of paper intended for food contact. Based on the rapid degradation of peroxyacetic acid, no residues are expected to be present in paper. As a result risk from dietary exposure is not of concern.

4.4 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

An aggregate dietary exposure and risk assessment is not required for peroxyacetic acid since there are no registered food uses and residential exposure is not of concern based on the registered use pattern. Moreover, while the product labels allow use in the manufacture of paper intended for food contact, as mentioned above, based on the rapid degradation of peroxyacetic acid, no residues are expected to be present in paper.

4.5 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that peroxyacetic acid shares a common mechanism of toxicity with other pest control products. Therefore there is no requirement for a cumulative assessment at this time.

5.0 Environment

5.1 Environmental Fate and Toxicology

Peroxyacetic acid undergoes hydrolysis, spontaneous decomposition, and metal-catalyzed decomposition in the aquatic environment, where it decomposes to acetic acid and water. Peroxyacetic acid is not persistent and has a very low potential to bioaccumulate in organisms.

Please refer to Proposed Registration Decision Document PRDD2000-02, *VigorOx* and Proposed Registration Decision PRD2012-28, *Proxitane* for environmental fate and ecological toxicity information for peroxyacetic acid.

5.2 Environmental Exposure and Risk Assessment

Environmental exposure and risk from the use of peroxyacetic acid in industrial settings (that is, recirculating cooling water systems, pulp and paper mills, waste water sewage treatment and on-shore oilfield and gas-field well operations) was previously assessed.

Exposure to terrestrial organisms from the use of peroxyacetic acid in recirculating cooling water systems, pulp and paper mills, and waste water and sewage treatment facilities is expected to be low. Risk from potential exposure to aquatic organisms from the discharge of effluents is not expected to be of concern under current conditions of use.

The use of peroxyacetic acid in on-shore oilfield and gas-field well operations could result in potential exposure to terrestrial and aquatic habitats due to the discharge of spent treatment fluids during operations. Concentrations of peroxyacetic acid in waste fluids from use in oil and gas operations are expected to be low, as peroxyacetic acid breaks down quickly in aquatic and terrestrial environments, and residues are not expected to accumulate in organisms. As such, peroxyacetic acid used in on-shore oil and gas field operations is not expected to pose a concern to the environment under current conditions of use.

Label amendments are proposed to meet current labelling standards and further protect aquatic habitats. The proposed label amendments are listed in Appendix II.

6.0 Value

Peroxyacetic acid is a slimicide co-formulated with hydrogen peroxide for control of algal, bacterial, fungal and yeast growth. There are numerous alternative products currently registered in Canada for use as slimicides in pulp and paper mill systems and recirculating cooling water systems, which cover a wide range of chemical entities from chlorine- and bromine-based oxidizing compounds to surfactants such as quaternary ammonium compounds that act on cell membranes.

Peroxyacetic acid is of value for the treatment of municipal wastewater effluent, as there is only one other active ingredient, sodium hypochlorite, currently registered for this use.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

Peroxyacetic acid was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and does not meet the Track 1 criteria. The active ingredient dissipates rapidly in the environment and does not bioaccumulate.

8.0 Incident Reports

Starting 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to PMRA within a set time frame.

As of 17 May 2017, there were no incidents submitted for peroxyacetic acid.

9.0 Organization for Economic Co-operation and Development Status of Peroxyacetic Acid

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

Peroxyacetic acid is currently acceptable for use in other OECD member countries, including the United States, Australia and European Union Member States. As of 17 May 2017, no decision by an OECD member country to prohibit all uses of peroxyacetic acid for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

The PMRA has determined that products containing peroxyacetic acid for sale and use in Canada are acceptable for continued registration provided that the proposed label amendments described in Appendix II are implemented.

List of Abbreviations

CAS	Chemical Abstracts Service
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*-octanol–water partition coefficient
LLC	Limited Liability Company
NIOSH	National Institute for Occupational Safety and Health
nm	nanometre(s)
OECD	Organization for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
PRVD	Proposed Re-evaluation Decision
TGAI	Technical Grade Active Ingredient
ULC	Unlimited Liability Company
UV	ultraviolet

Appendix I Registered Peroxyacetic Acid Products as of 17 May 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
26165	Technical Grade Active Ingredient	Peroxychem, LLC	Vigorox SP Paper System Biocide	Solution	Peroxyacetic acid 5.10% Hydrogen Peroxide 21.7%
26978			Vigorox SP-15 Paper System Biocide		Peroxyacetic acid 15% Hydrogen Peroxide 10%
31329			Vigorox 15/23 Antimicrobial Agent		Peroxyacetic acid 15.0% Hydrogen Peroxide 23.0%
31330	Commercial		Vigorox WWT II		Peroxyacetic acid 15.0% Hydrogen Peroxide 23.0%
32715			Vigorox Oil & Gas		Peroxyacetic acid 10% Hydrogen Peroxide 15%
26166	Commercial	Nalco Canada ULC	Nalco7650 Pulp & Paper Microbiocide		Peroxyacetic acid 5.1% Hydrogen Peroxide 21.7%
30066	Commercial	Kemira Chemicals Inc.	Fennosan PAA 15-C		Peroxyacetic acid 15% Hydrogen Peroxide 10%
28826	Technical Grade Active Ingredient	Evonik Canada Inc.	Peraclean		Peroxyacetic acid 15% Hydrogen Peroxide 22%
30675	Technical Grade Active Ingredient	Solvay Chemicals Inc.	Proxitane		Peroxyacetic acid 12.0% Hydrogen Peroxide 20.0%
30676	Commercial		Proxitane WW-12		Peroxyacetic acid 12.0% Hydrogen Peroxide 20.0%

Appendix II Label Amendments for Products Containing Peroxyacetic Acid

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) The following statements must be included in a section entitled **ENVIRONMENTAL PRECAUTIONS:**

Toxic to aquatic organisms.

II) The following statements must be included under **DIRECTIONS FOR USE** the following text must be added:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluent containing this product or the biocide produced into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters unless the effluent has been detoxified by suitable means.

III) The following statements must be included in a section entitled **DISPOSAL:**

For returnable containers:

DO NOT reuse this container for any purpose. For disposal, this empty container may be returned to the point of purchase (distributor/dealer).

For containers that can be refilled for the user by the distributor/dealer:

For disposal, this container may be returned to the point of purchase (distributor/dealer). It must be refilled by the distributor/dealer with the same product. Do not reuse this container for any other purpose.

Disposal of unused, unwanted product:

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

For non-returnable non-recyclable or non-refillable containers:

Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.

Follow provincial instruction for any required additional cleaning of the container prior to its disposal.

Make the empty container unsuitable for further use.

Dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY THE REGISTRANT

Unpublished information

PMRA Document Number	Reference
1618461	1996, HPX/PCA-FMC-7 FMC Corporation VigorOx - SP Paper System Biocide Amendment to Canadian Registration Application 834.1 FMC, DACO: 2.0,2.1,2.10, 2.11,2.12,2.14,2.15,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1882229	PCA-FMCS-8 CHANGE TO PCA-FMC-8 HISTORICAL CHEMISTRY FILE - Appendix 2 Manufacturing Summary, Specifications, Quality Control, Analytical Methodology, Chemical and Physical Properties, DACO: 2.11.1,2.12,2.13,2.13.4,2.14.1,2.14.10,2.14.12, 2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
1882236	1996, PCA-FMCS-8 CHANGE TO PCA-FMC-8 HISTORICAL CHEMISTRY FILE - Appendix 1 and 4 Manufacturing Summary, Quality Control, Analytical Data and Methodology, Chemical and Physical Properties Summary, DACO: 2.11.1,2.13,2.14 CBI
2663975	2016, Manufacturing Methods and List of Suppliers, DACO: 2.11 CBI
2663976	2016, Batch Data, DACO: 2.13.3 CBI
2663977	2016, Assey for [CBI Removed] in 5% PAA [CBI Removed], DACO: 2.13.4
2680028	2016, Batch Data, DACO: 2.13.3 CBI
2709971	2016, Manufacturing Methods, DACO: 2.11.3 CBI
1881766	HPX+PCA-FMC-13 HISTORICAL CHEMISTRY FILE - Manufacturing Methods VigorOx SP-15, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
1881789	HPX+PCA-FMC-13 HISTORICAL CHEMISTRY FILE - Chemical and Physical Properties VigorOx SP-15, DACO: 2.14 CBI
2663606	2016, Batch Data, DACO: 2.13.3 CBI
2663607	2016, Assey for [CBI Removed] in 15% PAA [CBI Removed], DACO: 2.13.4
1102441	Description of Starting Materials;, DACO: 2.11.2 CBI
1118001	Chemical and Physical Properties. Loaded electronically from the company. Section 2.14.13 is missing, but it was coded as 2.14., DACO: 2.14 CBI
1338562	PERACLEAN 15 production scheme 44,840 lbs. batch, DACO: 2.11.3 CBI
1338567	2006, Analytical data of PERACLEAN 15 EPA, DACO: 2.13.3 CBI
2119867	1999, Description of the Formulation Process For Proxitane WW-12, DACO: 2.11.1,2.11.3 CBI
2119868	1995, Product Specific Chemistry Data Proxitane WW-12, DACO: 2.11.2,2.11.4,2.13.1, 2.13.2 CBI
2119870	1998, Product Chemistry for End-Use Liquids, DACO: 2.13.3,2.14.1,2.14.13,2.14.2,2.14.6 CBI
2119871	1995, Physical and Chemical Characteristics Proxitane WW-12, DACO: 2.14.10,2.14.11, 2.14.12,2.14.3,2.14.4,2.14.5,2.14.7,2.14.8,2.14.9 CBI
2175252	2012, Impurites Analysis, DACO: 2.13.4 CBI

2644081	2016, Proxitane¿¿ Registration Number 30675 Analysis of 5 Production Batches, DACO: 2.13.3 CBI
2266533	Part 2 - Chemistry Requirements for TGAI, DACO: 2.1,2.10,2.14.1,2.14.10,2.14.11, 2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2 ,2.3, 2.3.1,2.4,2.5,2.6, 2.7,2.8,2.9
2266535	2008, Product Identity, Composition, and Formulation, DACO: 2.11.1,2.11.2,2.11.3,2.11.4, 2.12.1,2.13.1,2.13.2,2.13.3
2266536	2008, Product Identity, Composition, and Formulation, DACO: 2.11.2,2.11.3,2.11.4,2.12.1, 2.13.1,2.13.2,2.13.3 CBI
2266572	Part 3 - Chemistry Requirements for EP, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.1,3.5.3, 3.5.4,3.5.5
2266576	Part 3.5.10: Storage Stability and Part 3.5.14: Corrosion Characteristics, DACO: 3.5.10,3.5.14
2320148	2013, VigorOx 15/23 Antimicrobial Agent Starting Materials, DACO: 2.11.3 CBI
2320151	2013, VigorOx 15/23 Antimicrobial Agent Batch Data, DACO: 2.13.3 CBI
2398048	2014, Results of 5 batch [CBI Removed] analysis on VigorOx 15/23 Antimicrobial Agent, DACO: 2.13.4 CBI

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

2700241	2016. Evaluation Report for Category B, Subcategory 3.12 Application
2396955	2014. Evaluation Report for Category A, Subcategory 2.0 Application
2397593	2014. Evaluation Report for Category A, Subcategory 2.0 Application
2248469	PRD2012-28 Proposed Regulatory Decision - Proxitane
2032552	2013. Evaluation Report for Category B, Subcategory 2.6 Application
654843	PRDD2000-02 Proposed Regulatory Decision Document Vigorox™